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PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Artcle 36 and Rule 70)

Applicant's or agent's file reference LL03PCT003	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. **PCT/KR2003/000998**	International filing date *(day/month/year)* **21 MAY 2003 (21.05.2003)**	Priority date *(day/month/year)* 26 JULY 2002 (26.07.2002)

International Patent Classification (IPC) or national classification and IPC

IPC7 C08B 37/08

Applicant

LG Life Sciences Ltd. et al

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 4 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of _____ sheets.

3. This report contains indications relating to the following items:

   I ☒ Basis of the report
   II ☐ Priority
   III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   IV ☐ Lack of unity of invention
   V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   VI ☐ Certain documents cited
   VII ☐ Certain defects in the international application
   VIII ☐ Certain observations on the international application

Date of submission of the demamd	Date of completion of this report
06 FEBRUARY 2004 (06.02.2004)	09 NOVEMBER 2004 (09.11.2004)

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International aplication No.
PCT/KR2003/000998

I. Basis of the report

1. With regard to the elements of the international application:*

- [X] the international application as originally filed
- [ ] the description:
  pages _____ , as originally filed
  pages _____ , filed with the demand
  pages _____, filed with the letter of _____
- [ ] the claims:
  pages _____ , as originally filed
  pages _____ , as amended (together with any statment) under Article 19
  pages _____ , filed with the demand
  pages _____, filed with the letter of _____
- [ ] the drawings:
  pages _____ , as originally filed
  pages _____ , filed with the demand
  pages _____, filed with the letter of _____
- [ ] the sequence listing part of the description:
  pages _____ , as originally filed
  pages _____ , filed with the demand
  pages _____, filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is

- [ ] the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- [ ] the language of publication of the international application(under Rule 48.3(b)).
- [ ] the language of the translation furnished for the purposes of international preliminary examination(under Rules 55.2 and/ or 55.3).

3. With regard to any **nucleotide** and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- [ ] contained inthe international application in written form.
- [ ] filed together with the international application in computer readable form.
- [ ] furnished subsequently to this Authority in written form.
- [ ] furnished subsequently to this Authority in computer readable form
- [ ] The statement that the subsequently furnished written sequence listing does not go beyond the disc losure in the international applicationas as filed has been furinshed.
- [ ] The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. [ ] The amendments have resulted in the cancellation of:
   - [ ] the description, pages _____
   - [ ] the claims, Nos. _____
   - [ ] the drawings, sheets _____

5. [ ] This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box(Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed." and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item I and annexed to this report.*

INTERNATIONAL PRELIMINARY EXAMINATION

International aplication No.
PCT/KR2003/000998

V. **Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	None	YES
	Claims	1-13	NO
Inventive step (IS)	Claims	None	YES
	Claims	None	NO
Industrial applicability (IA)	Claims	1-13	YES
	Claims	None	NO

2. Citations and explanations (Rule 70.7)

Reference is made to the following document:

D1: WO 02/30990 A1 (LG Chem. Investment, LTD.) 18 April 2002

1. Novelty

The subject matter of claims 1 to 13 does not meet the requirements of PCT Article 33(2) in respect of novelty. The reason is as follows:

The subject matter of claims 1 to 13 relates to hyaluronic acid derivative gels which are formed by coupling an amine group-containing saccharide compound to a hyaluronic acid or a cationic salt thereof, via amidation reaction, and a method for preparing the same.

However, D1 discloses water-insoluble, crosslinked amide derivatives of hyaluronic acid and a manufacturing method thereof, where the amide derivatives of hyaluronic acid are characterized by crosslinking, of polymer or oligomer having two or more amine groups, with hyaluronic acid or its hyaluronate salts through amidation reaction.

(1) The subject matter of claim 1 relates to a method for preparing a hyaluronic acid derivative gel, by mixing a hyaluronic acid or its cationic salt, and a saccharide compound containing amine groups, activating the carboxyl group of the hyaluronic acid, and consequently reacting the activated carboxyl group of the hyaluronic acid with the amine group of the saccharide compound, which is disclosed in claims 1 to 2 of D1.

(Continued on Supplemental Sheet.)

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of:

Box V.

(2) The subject matter of claim 2 relates to a method, wherein the cationic salt of hyaluronic acid is selected from sodium, potassium, ammonium etc., and the method is also listed in page 1 (paragraph 20) of D1.

(3) The final reaction concentration and average molecular weight of hyaluronic acid or its salt in claims 3 and 4 are disclosed in claim 6 of D1. Although the ranges in this invention are narrower than D1, there is no reason found for making the ranges narrower.

(4) The subject matter of claim 5 is revealed in claim 4 of D1, wherein the amine group-containing saccharide compound is selected from chitosan, hyaluronic acid or their derivatives.

(5) The subject matter of claim 6 is disclosed in claim 5 in D1.

(6) The subject matter of claims 7 to 9, wherein the activation of the carboxyl groups is accomplished by adding one or more agents for activating carboxyl groups, are included in claims 7 to 9 of D1.

(7) The final reaction concentration of EDC or NHS is also listed in claim 10 of D1. Although the ranges in this invention are narrower than D1, there is no meaningful reason for making the ranges narrower.

(8) The subject matter of claim 12 is disclosed in examples 10 and 11 of D1.

(9) The subject matter of claim 13 is about the hyaluronic acid derivative gel produced by the aforementioned methods, which is disclosed in claim 22 of D1.

2. Inventive Step

Claims 1 to 13 lack an inventive step [PCT Article 33(3)].

3. Industrial Applicability

Claims 1 to 13 are considered to be industrially applicable [PCT Article 33(4)].